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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,235	10/29/2001	Barbara S. Fox	110001.123	9886

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EXAMINER	
WALLS, DIONNE A	

ART UNIT	PAPER NUMBER
1731	

DATE MAILED: 11/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

AS

Office Action Summary	Application No.	Applicant(s)	
	10/045,235	FOX, BARBARA S.	
	Examiner	Art Unit	
	Dionne A. Walls	1731	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- *Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).*
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/285016. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are anticipated by the claims of 10/285,016 since the instant claims are broader and more generic than those of 10/285,016.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-9, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (US. Pat. No. 6,106,845) in view of Ruecroft et al (US. Pat. No. 5,663,356).

Wong et al discloses all that is recited in the claims (see cols 3-8 and figs. 1A-3B) except it may not state that the oral active agent is nicotine. However, Wong et al does state that the active agent can be one of any large number of substances which provide some pharmacologic effect, such as drugs that act on the central nervous system. Further, Ruecroft et al discloses, in its "Background of Invention" section, that nicotine is known to have a number of pharmacological effects, and has been used in the treatment of neurological disorders (see col. 1, lines 39-65). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize nicotine as the active agent because of the benefits associated the substance in the treatment of certain diseases.

Regarding claims 2-3, based on the disclosure of a tube shape of the chamber of Wong et al, coupled with the disclosure that states that the device can be between about 10 – 30 cm in length, it follows that said chamber approximates the shape of both a conventional cigarette and a drinking straw, since both are merely slender cylindrical objects and the typical length of both cigarettes or straws would lie somewhere within this range.

Regarding claims 6-8, while Wong et al modified by Ruecroft et al may state that the active agent may be coated nicotine particles, it may not specifically mention the

claimed coating materials. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to utilize any one of the listed substances (i.e. sugar) to provide a film of coating material on the particulate since these materials are well-known in many arts for serving this purpose.

Regarding claims 9, and 14-15, Wong et al modified by Ruecroft et al teaches that, preferably, the amount of active agent to be delivered to the user (i.e. the amount contained in the tubular chamber) is between 25-5000 mg (corresponding to the claimed "4-144 mg"). While the combined references may not specifically teach that the tubular chamber contains 4-12 mg of nicotine, Wong et al does teach that the amount of active agent will vary depending on the particular agent, the severity of the condition and the desired therapeutic effect (see col. 7, lines 43-48). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver the nicotine agent in the claimed amount, after routine experimentation to determine the optimal amount needed to achieve the desired result.

5. Claims 10-12, 16-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wong et al (US. Pat. No. 6,106,845) in view of Ruecroft et al (US. Pat. No. 5,663,356), further in view of Westman et al (US. Pat. No. 6,211,194).

These claims differ from Wong et al modified by Ruecroft et al because of language that recites that a solution of nicotine (as a suspension) is formed when the liquid enters the chamber and contacts the nicotine, said nicotine being selected from the group consisting of levo nicotine, dextro nicotine, racemic mixtures thereof, and pharmaceutically acceptable salts thereof, and said solution having acidic pH and

including a flavoring. However, Wong et al does disclose that the active agents can be delivered in various forms, such as soluble or insoluble molecules (see col. 7, lines 39-40). This would have suggested to one having ordinary skill in the art that said active agent molecules can be combined, with the liquid, to form a solution of suspended nicotine particles. Further, Westman et al discloses a solution containing nicotine particles for treating various medical ailments, said nicotine employed in the solution being levo or dextro nicotine, or a racemic mixture of both; said nicotine solution having a pH adjusted to be acidic, containing a flavoring and delivered to the user so as to result in blood levels of about 2-30 ng per 1 ml of blood (see cols. 5 and 6). It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the nicotine solution in Westman et al into the device of Wong et al modified by Ruecroft et al since such solution, containing an active agent, is designed to treat various medical conditions – which is consistent with the teaching of Wong et al - and is provided as conveniently dispensed, palatably acceptable, well-tolerated formulations.

Regarding claim 22, while not explicitly stated, it follows that not only would liquid enter the tubular chamber when the solution is administered to the user, but air (corresponding to the claimed "gas") would also be delivered to the user, obviously provided from an external source (i.e. the atmosphere).

Response to Arguments

6. Applicant's arguments filed on August 4th, 2003, have been fully considered. Those regarding the Slutsky reference are persuasive. However, those regarding the Wong, Ruecroft and Westman references are not persuasive.

- Applicant argues that there would be no motivation to combine the teachings of Wong, relating to particular delivery devices, with the teachings of Ruecroft et al, directed to methods of preparing certain nicotine compounds – because the two references belong to distinct and unrelated fields. However, the Examiner disagrees. As stated in the above rejection, it seems clear that Wong contemplates a myriad of substances, which would provide pharmacologic affect, for use in the disclosed device, for it proceeds to recite a huge "laundry list" of possible active substances that would be suitable for use in such device (see col. 6 and 7). Clearly Wong has no intention of limiting the "active agent" to one particular type of substance. While there may have been no specific statement of the use of "nicotine" as the active agent, the Examiner relies on the Ruecroft et al reference merely for its teaching of what is already known in the art – not for the merits of the Ruecroft invention itself. Ruecroft et al articulates the well-known fact that nicotine has been proposed to have a number of pharmacological effects as it relates to the central nervous system of a human being. And, the Examiner contends, that with this well-known knowledge, one having ordinary skill in the art would have been motivated to use it in the device of Wong – which also utilizes substances which affect, for medicinal use, the central nervous system.

- Applicant argues that Wong teaches away from the use of nicotine since it discloses a device particularly useful for delivering large doses of drugs to patients with difficulty swallowing tablets, and nicotine would not be difficult to swallow,but the Examiner believes that this would not have dissuaded one from utilizing the device of Wong with nicotine as an active agent. Wong merely suggests its device has a

particular benefit (i.e. ease of use especially for those having difficulty in swallowing pills), but this is not to say that there may not be other reasons that one may choose to use the Wong device, i.e. ease of use and manufacture.

- Applicant argues that Wong teaches away from a device containing a solution of an active agent. However, as stated above, the Examiner believes that Wong contemplates an active agent in solution when it states that the agents can be in various forms, such as soluble molecules, which infers a dissolved agent (solute) in a solvent. Further, Westman discloses that nicotine solutions are known for their use in patients for medicinal purposes. So, one having ordinary skill in the art would have been motivated to use such a formulation in the device of Wong and Ruecroft et al – in order to receive the benefits of such a substance in the treatment of drug/tobacco addiction.

- Lastly, while Applicant has submitted a "Declaration", under 37 CFR 1.132 filed August 4th, 2003, it is insufficient to overcome the rejection of the claims, as set forth in the last Office action because:

- it is not clear how Applicant can arrive at the conclusion that "unexpected synergistic results" are obtained beyond what would be expected from combining the teaching of the prior art when all Applicant has shown is merely that a human subject who has received a certain amount of nicotine per straw (via "The Straw") will have reduced cravings as compared to a human subject who has only been administered a placebo. Applicant has not compared cigarette cravings in human subjects who have been administered nicotine via "The Straw" versus those who have been administered nicotine via the product of the closest prior art, i.e. Wong modified by Ruecroft. Also,

the Examiner notes, Applicant asserts that its studies found that "4 mg nicotine gum...did not reduce cigarette craving beyond that seen with placebo gum", yet in the chart on page 102, of the Article of Exhibit B", is does appear that nicotine gum reduced the cigarette cravings more than that seen with placebo gum. The same article indicates that nicotine spray further reduced said cravings. This evidence further supports the Examiner's contention that it would be "expected" that a straw which delivers nicotine, as Wong modified by Ruecroft et al, would obviously reduce cigarette cravings.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dionne A. Walls whose telephone number is (703) 305-

0933. The examiner can normally be reached on Mon-Fri, 7AM - 4:30PM (Every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Steven P. Griffin can be reached on (703) 308-1164. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0661.

Dionne A. Walls
October 31, 2003

STEVEN P. GRIFFIN
SUPERVISORY PATENT EXAMINER
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